

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|--|--|
| Date of mailing (day/month/year) 15 May 2001 (15.05.01) | |
| International application No. PCT/IL00/00494 | Applicant's or agent's file reference 38807 |
| International filing date (day/month/year) 15 August 2000 (15.08.00) | Priority date (day/month/year) 19 August 1999 (19.08.99) |
| Applicant BLATT, Yoav et al | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

02 February 2001 (02.02.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 | Authorized officer Claudio Borton Telephone No.: (41-22) 338.83.38 |
|---|--|

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF DEFECTS IN DEMAND

(PCT Rule 60.1(d))

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as International Preliminary Examining Authority

Date of mailing

(day/month/year) 15 May 2001 (15.05.01)

International application No.

PCT/IL00/00494

International filing date

(day/month/year) 15 August 2000 (15.08.00)

Applicant

BIO DAR LTD. et al

The International Bureau hereby notifies the International Preliminary Examining Authority that it has found that the demand is defective for the reasons indicated below:

1. ☐ It does not contain the election of at least one Contracting State bound by Chapter II (Rule 53.2(a)(iv) and 53.7).
2. ☐ It does not permit the identification of the international application to which it relates (Rule 60.1(b)).
3. ☐ It does not contain the required petition (Rules 53.2(a)(i) and 53.3).
4. ☐ It does not contain the required indications concerning the agent as specified in the Annex (Rules 53.2(a)(ii) and 53.5).
5. ☐ It does not contain the required indications concerning the international application as specified in the Annex (Rules 53.2(a)(iii) and 53.6).
6. ☐ It is not submitted in the required language which is _____ (Rule 55.1).
7. ☐ It is not made on the printed form (Rule 53.1(a)).
8. ☐ It is presented as a computer print-out the particulars of which do not comply with the Administrative Instructions (Rule 53.1(a)).
9. ☐ It does not contain the required indications concerning the applicant as specified in the Annex (Rules 53.2(a)(ii) and 53.4).
10. ☒ It does not contain the required signature as specified in the Annex (Rules 53.2(b) and 53.8).

Other observations, if necessary:

The International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorised officer

Claudio Borton

Telephone No.: (41-22) 338.83.38

NOTIFICATION OF DEFECTS IN DEMAND

International application No.

PCT/IL00/00494

Continuation of item 4: As to indications concerning the agent (Rule 4.4), the demand:

- a. ☐ does not properly indicate the agent's name (specify):

- b. ☐ does not indicate the agent's address.
- c. ☐ does not properly indicate the agent's address (specify):

Continuation of item 5: As to indications concerning the international application, the demand does not indicate:

- a. ☐ the international filing date.
- b. ☐ the international application number.
- c. ☐ the name of the receiving Office, where the international application number was not known to the applicant at the time the demand was filed.
- d. ☐ the title of the invention.

Continuation of item 9: As to indications concerning the applicant (Rules 4.4 and 4.5), the demand:

- a. ☐ does not indicate all the applicants for the elected States.
- b. ☐ does not properly indicate the applicant's name (specify):

- c. ☐ does not indicate the applicant's address.
- d. ☐ does not properly indicate the applicant's address (specify):

- e. ☐ does not indicate the applicant's nationality.
- f. ☐ does not indicate the applicant's residence.

Continuation of item 10: As to requirements concerning signature (Rules 4.15 and 90.4), the demand:

- a. ☐ is not signed.
- b. ☐ is not signed by all the applicants for the elected States.
- c. ☐ is not accompanied by the statement referred to in the check list in Box No. VI of the demand explaining the lack of the signature of an applicant for the election of the United States of America.
- d. ☒ is signed by what appears to be an agent/common representative but
 - ☒ the demand is not accompanied by a power of attorney appointing him. *ZIELINSKI, W.T.*
 - ☐ the power of attorney accompanying the demand is not signed by all the applicants for the elected States.

PATENT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS(PCT Rule 62 and
Administrative Instructions, Section 417)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

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|--|---|
| Date of mailing (day/month/year) 15 May 2001 (15.05.01) | International filing date (day/month/year) 15 August 2000 (15.08.00) |
| International application No. PCT/IL00/00494 | |
| Applicant BIO DAR LTD. et al | |

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

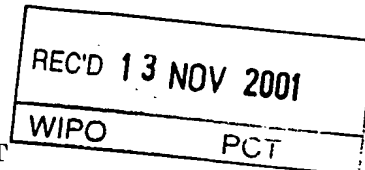
| | |
|---|--------------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Claudio Borton |
| Facsimile No. (41-22) 740.14.35 | Telephone No. (41-22) 338.83.38 |

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



| | | |
|--|--|--|
| Applicant's or agent's file reference 6727/21239WO | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/IL00/0049+ | International filing date (day/month/year) 15 AUGUST 2000 | Priority date (day/month/year) [NONE] 19 Aug 1999 |
| International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet. | | |
| Applicant BIO DAR LTD. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|--|
| Date of submission of the demand 02 FEBRUARY 2001 | Date of completion of this report 10 OCTOBER 2001 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer Susan Tran |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 305-1235 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL00/00494

I. Basis of the report**1. With regard to the elements of the international application:***☐ the international application as originally filed☒ the description:pages 1-14, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the claims:pages 15-19, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the drawings:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/~~figs~~ NONE**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL00/00494

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 15-32

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination (*specify*).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _ are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 15-32.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL00/00+9+

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-14</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-14</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-14</u> | YES |
| | Claims <u>NONE</u> | NO |

2. citations and explanations (Rule 70.7)

Claims 1-14 lack an inventive step under PCT Article 33(3) as being obvious over Thurn et al. (US 6,004,558), in view of Mazer et al. (US 5,707,353).

Thurn teaches a pharmaceutical composition comprising an extract of isoflavone with one or more pharmaceutically acceptable carriers, excipients, auxiliaries, and/or diluents (column 2, lines 14-63). The composition is for oral administration including tablets, capsules, powder or granules (column 4, lines 42-45). Suitable carriers are disclosed in column 4, lines 65 through column 5, lines 1-32. The process for obtaining the composition is disclosed in column 7, lines 24-43.

The reference is silent as to the teaching of the controlled release of active ingredient.

Mazer teaches a controlled release composition for oral administration including tablets, capsules, or granules that can be coated to provide sustained or delayed release (column 10, lines 55 through column 11, lines 1-40). The composition comprising one or more beneficial agents including iso-flavone (column 13, lines 1-55). Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Thurn's composition with the coating in view of the teaching of Mazer to obtain a desired rate of release of active agent. The skilled artisan in this art would have been motivated to prepare a controlled release composition to achieve high bioavailability of the active agent.

----- NEW CITATIONS -----
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL00/00+9+

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 9/16, 9/20, 9/22, 9/26, 9/48, 9/52, 9/54, 9/56, 9/58, 9/64; A01N 25/00 and US Cl.: 424/451, 453, 457, 458, 459, 461, 462, 464, 465, 468, 469, 470, 490, 494, 497; 514/783

INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/IL00/00494

| A. CLASSIFICATION OF SUBJECT MATTER | | |
|--|---|---|
| IPC(7) :Please See Extra Sheet. | | |
| US CL :Please See Extra Sheet. | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED | | |
| Minimum documentation searched (classification system followed by classification symbols) | | |
| U.S. : 424/451, 453, 457, 458, 459, 461, 462, 464, 465, 468, 469, 470, 490, 494, 497; 514/783 | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) | | |
| West | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| Y | US 6,004,558 A (THURN et al.) 21 December 1999, see column 2, lines 14-63; column 3, lines 19 through column 4, lines 1-64; column 5, lines 1-60, column 7, lines 24-43. | 1-14 |
| Y | US 5,707,353 A (MAZER et al.) 13 January 1998; see column 9, lines 12-62; column 10, lines 55 through column 11, lines 1-40; column 12, lines 66 through column 13, lines 1-55. | 1-5, 11-14 |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex. | | |
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "G" document member of the same patent family | |
| Date of the actual completion of the international search | | Date of mailing of the international search report |
| 20 DECEMBER 2000 | | 24 JAN 2001 |
| Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 | | Authorized officer SUSAN TRAN Telephone No. (703) 308-1255 JOYCE BRIDGERS PARALEGAL SPECIALIST CHEMICAL PATENT |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL00/00494

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL00/00494

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (7):

A61K 9/16, 9/20, 9/22, 9/26, 9/48, 9/52, 9/54, 9/56, 9/58, 9/64; A01N 25/00

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

424/451, 453, 457, 458, 459, 461, 462, 464, 465, 468, 469, 470, 490, 494, 497; 514/783

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions, and which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-14, drawn to a controlled release formulation of isoflavone-enriched fraction or mixture thereof.

Group II, claim(s) 15-32, drawn to a controlled release formulation of isoflavone-enriched fraction or mixture thereof coated with film comprising water soluble polymer and water insoluble polymer.

The inventions listed as Groups I and II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they do not share the same essential feature element(s) that define the "special technical feature" necessary to specify a contribution over the prior art. The feature common to all the groups is granulated isoflavone which is known in the art and, therefore, cannot be said to be the special technical feature which makes a contribution over the prior art. All other features differ from each other, in example, coating granulate, tablet, capsule, each of which are known in the prior art. Thus, these claims lack the corresponding special technical feature(s) necessary to link them together to fulfill the Unity of Invention requirement.